

**Biomedical Study Closure Form**

**\*Note, if your study is on-going please fill out the study renewal form rather than this form.**

**Please type in your responses, print, and then send the original signed copy to our office or email to** [**research.ethics@uregina.ca**](mailto:research.ethics@uregina.ca)

**Double click on boxes to check.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1. Title:** | | | | |
| **2. Bio #:** | | | | **3: Protocol #:** |
| **4. Contact Information:** | | | | |
|  | **Name:** | **Department:** | **Phone Number, Email, Fax Number**  **(Provide only if different from previously submitted information):** | |
| **Principal Investigator:** |  |  |  | |
| **Contact Person:** |  |  |  | |
| **5. Sponsor/Funding Agency:** | | | | |
| **6. What was the target enrollment for the study? \_\_\_\_** | | | | |
| **7. How many research participants were screened for the study? \_\_\_\_** | | | | |
| **8. How many research participants were enrolled in the study? \_\_\_\_** | | | | |
| **9. How many research participants have completed the study? \_\_\_\_** | | | | |
| **10. How many research participants have been withdrawn from or discontinued the study? \_\_\_\_\_\_\_\_**  **Please provide a reason for each withdrawal (if known):**  **Need for Other Treatment, number \_\_\_\_\_**  **Withdrawn Consent/Dropped Out, number: \_\_\_\_\_\_**  **Serious Adverse Event, number: ­­\_\_\_\_\_\_**  **Other, number \_\_\_\_\_ (Specify reason, if known)** | | | | |
| **11. Have any ethical concerns arisen in the course of the study that have not been reported to the Bio REB?**  **Yes**  **No**  **If Yes, please describe concerns in detail.** | | | | |
| **12. Have all serious adverse events been reported to the Bio REB?**  **Yes**  **No**  **Please attach a Serious Adverse Event Report form for any unreported serious adverse events.** | | | | |
| **13. Have all major protocol deviations been reported to the Bio REB?  Yes  No**  **Please attach a Protocol Deviation Report form for any unreported major protocol deviations.** | | | | |
| **14. Please explain why the study is being closed if other than study completed.**  **Data collection completed**  **Discontinued due to insufficient enrollment**  **Cancelled prior to initiation**  **Terminated by sponsor**  **Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_** | | | | |
| **15. Provide a brief summary of study results.** | | | | |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Principal Investigator and/or Supervisor Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Signature of Student Investigator Date***